## NEWS RELEASE



## OFFICE OF THE UNITED STATES ATTORNEY SOUTHERN DISTRICT OF CALIFORNIA

San Diego, California

United States Attorney Carol C. Lam

For Further Information, Contact: Assistant U. S. Attorney Phillip L.B. Halpern (619) 557-5165 or Assistant U.S. Attorney Kyle W. Hoffman (619) 557-6157

For Immediate Release

## NEWS RELEASE SUMMARY - July 22, 2004

United States Attorney Carol C. Lam announced that a Grand Jury sitting in the Southern District of California returned an eight-count indictment against San Diego-based corporation Metabolife International, Inc., and its founder, Michael J. Ellis. The indictment charges both defendants with six counts of making false, fictitious and fraudulent representations to the Food and Drug Administration ("FDA"), and two counts of corruptly endeavoring to influence, obstruct and impede proceedings concerning the regulation of dietary supplements containing ephedra being conducted by the FDA, an agency of the Department of Health and Human Services. Until FDA banned the sale of ephedra in the United States in 2003, Metabolife was one of the largest retailers of dietary supplements in the United States, based largely on sales of its ephedra-based product, Metabolife 356.

According to Assistant United States Attorneys Phillip L.B. Halpern and Kyle W. Hoffman, who are prosecuting the case, Metabolife and Ellis are charged with falsely representing a number of different material

facts to the FDA in letters dated April 17, 1998 and February 9, 1999. These representations included false

statements by the Defendants that "Metabolife ha[d] never received one notice from a consumer that any

serious adverse health event has occurred because of the ingestion of Metabolife 356" and that the company

had a "claims-free history."

United States Attorney Lam said, "It is never acceptable for corporations to lie to regulatory agencies,

but it is particularly egregious when those lies threaten the public health."

"One of FDA's highest priorities involves our responsibility to ensure that information about products

we regulate is truthful and not misleading, because people depend on that information to make informed

choices," said Acting FDA Commissioner Dr. Lester M. Crawford. "We will pursue to the full extent of the

law those who would seek to mislead consumers by providing false information or impeding investigations

of risky products."

This case is being investigated by the FDA Office of Criminal Investigations and the IRS Criminal

Investigation Division. United States Attorney Lam stated that the investigation is continuing.

The defendants are scheduled to be arraigned before Magistrate Judge Louisa Porter in San Diego

on Tuesday, July 27, 2004 at 10:30 a.m.

**DEFENDANTS** 

Case Number: 03 CR 1088-J

Metabolife International, Inc.

San Diego, CA

Michael J. Ellis

SUMMARY OF CHARGES AND MAXIMUM PENALTIES

Making False Statements to the Food and Drug Administration in violation of

Title 18, United States Code, Section 1001 (Counts 1, 2, 3, 5, 6 and 7)

Maximum penalty is five years in prison and a fine not to exceed \$250,000.

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Obstruction of Agency Proceedings in violation of Title 18, United States Code, Section 1505 (counts 4 and 8)

Maximum penalty is five years in prison and a fine not to exceed \$250,000

## **PARTICIPATING AGENCIES**

Food and Drug Administration, Office of Criminal Investigation Internal Revenue Service, Criminal Investigation Division

An indictment itself is not evidence that the defendants committed the crimes charged. The defendants are presumed innocent until the Government meets its burden in court of proving guilt beyond a reasonable doubt.